



## **Evidence-based Practice Center Rapid Response Protocol**

### **Project Title: *Making Healthcare Safer IV: Fatigue and Sleepiness of Clinicians Due to Hours of Service***

#### **Review Questions**

1. What is the frequency and severity of harms associated with fatigue and sleepiness of clinicians due to hours of service?
2. What patient safety measures or indicators have been used to examine the harm associated with fatigue and sleepiness of clinicians?
3. What patient safety practices (PSPs) have been used to prevent or mitigate the harms associated with fatigue and sleepiness of clinicians due to hours of service and in what settings have they been used?
4. What is the rationale for the PSPs used to prevent or mitigate the harms associated with fatigue and sleepiness of clinicians due to hours of service?
5. What studies have assessed the effectiveness and unintended effects of the PSPs and what new evidence has been published since the search was done for the Making Healthcare Safer (MHS) II report in 2013?
6. What are common barriers and facilitators to implementing the PSPs?
7. What resources (e.g., cost, staff, time) are required for implementation?
8. What toolkits are available to support implementation of the PSPs?

## **Context and Domain Being Studied**

The Agency for Healthcare Research and Quality (AHRQ) Making Healthcare Safer (MHS) reports consolidate information for healthcare providers, health system administrators, researchers, and government agencies about PSPs that can improve patient safety across the healthcare system—from hospitals to primary care practices, long-term care facilities, and other healthcare settings. In Spring of 2023, AHRQ launched its fourth iteration of the MHS Report (MHS IV).

Fatigue and sleepiness of clinicians due to hours of service is a patient safety risk and associated PSPs were identified as high priority for inclusion in the MHS IV reports using a modified Delphi technique by a Technical Expert Panel (TEP) that met in December 2022. The TEP included 15 experts in patient safety with representatives of governmental agencies, healthcare stakeholders, clinical specialists, experts in patient safety issues, and a patient/consumer perspective. See the MHS IV Prioritization Report for additional details.<sup>1</sup>

Insufficient or disrupted sleep leads to a state of fatigue characterized by deficits in attention, memory, and cognitive speed.<sup>2</sup> This neurobehaviorally degraded state translates into poorer performance by clinicians<sup>3</sup> and ultimately contributes to medical errors.<sup>4</sup> Thirty six percent of healthcare practitioners and technicians and forty five percent of healthcare support occupations report chronic short sleep durations.<sup>5</sup> This is driven by long working hours, particularly for clinical trainees, and shift work schedules necessary to staff hospitals around the clock.

## **Overview of the Patient Safety Practice**

Fatigue is a safety risk in the workplace across industries,<sup>6</sup> and consequently general principles and practices for fatigue risk management systems have been developed<sup>7, 8</sup> and evaluated in different settings.<sup>9</sup> This PSP topic was addressed in the MHS I report, which provided a broad review of workplace fatigue including studies across industries, as very little research had been conducted within healthcare settings at the time.<sup>10</sup> The MHS I review covered interventions focused on hours of service (i.e., regulations limiting the maximum shift length or total hours worked, and comparisons of 8- versus 12-hour shift

lengths), the direction and speed of rotation through shift work (i.e., shift rotation directions moving 'forward' [day to evening to night] or 'backward' [day to night to evening]; slow versus fast shift rotations), sleep hygiene education, work lighting, napping, and medical therapies (e.g., melatonin, sedatives, and stimulants). That report concluded that there was an insufficient evidence base within healthcare settings, but fatigue management interventions from other work domains had high face-validity, low likelihood of harm, and high ease of implementation. The hours of service and fatigue topic received a brief update in MHS II, focusing on evaluations of regulatory limitations on resident duty hours.<sup>11</sup> Based on several systematic reviews of that literature, the MHS II review concluded that work hour limitations did not reduce mortality or improve safety; but there were fewer objective and self-reported medical errors with 16-hour shift lengths than with traditional 30-hour shifts. Patient safety risks due to fatigue and sleepiness of healthcare workers were not addressed in MHS III.

In the decade since the MHS II report, the high levels of burnout among clinicians have come into focus.<sup>12, 13</sup> While burnout is complex, sleep deprivation has been implicated in the development and sustainment of high levels of burnout<sup>14</sup> and it is possible the coronavirus disease of 2019 (COVID-19) pandemic has amplified these issues in part due to atypical work schedules.<sup>15</sup>

In the prioritization process, the MHS IV TEP did not suggest alterations to past definitions of this patient safety risk or associated PSPs. However, due to the limited time and funding allocated for this rapid response, the report will focus on PSPs targeting clinicians rather than other healthcare workers because patient outcomes are more directly related to the performance of clinicians than to the performance of non-clinical healthcare workers. Clinicians are defined as any person providing healthcare to patients (e.g., physician, nurse, physician assistant, respiratory therapist, or pharmacist). The report also will focus on clinicians in acute care hospital settings because that is where interventions on shift schedules and fatigue risk management practices are most likely to have been conducted.

## **Purpose of the Review**

The purpose of this rapid response is to summarize the most relevant and recent

literature on PSPs focused on fatigue and sleepiness of clinicians related to hours of service and how these PSPs can be implemented. The report should be of interest to healthcare system and hospital leaders who are wrestling with concerns about clinician burnout.

## **Methodologic Approach**

For this rapid response, strategic adjustments will be made to streamline traditional systematic review processes and deliver an evidence product in the allotted time. We will follow adjustments and streamlining processes proposed by the AHRQ Evidence-based Practice Center (EPC) Program. Adjustments include being as specific as possible about the questions, limiting the number of databases searched, modifying search strategies to focus on finding the most valuable studies (i.e., being flexible on sensitivity to increase the specificity of the search), and restricting the search to studies published since 2013 (when the search was done for the MHS II report) in English and performed in the United States, and having each study assessed by a single reviewer. Depending on the volume of literature, the EPC team may opt to have a randomly selected 10% sample of articles checked by a second reviewer or use the artificial intelligence (AI) feature of DistillerSR (AI Classifier Manager) as a second reviewer at the title and abstract screening stage.

We will search for recent high quality systematic reviews defined using the criteria for “Good” described below in the Risk of Bias Assessment section. However, if we do not find reviews that meet the full criteria for “Good”, we will consider reviews that do not include standard appraisal of included studies if they use comprehensive sources and search strategies, and explicit relevant selection criteria. We will rely primarily on the content of any such systematic review that is found. We will not perform an independent assessment of original studies cited in any such systematic review.

We will ask our content experts to answer Review Questions 1 and 2 by citing selected references that best answer the questions without conducting a systematic search for all evidence on the targeted harms and related patient safety measures or indicators. We will focus on the harms and patient safety measures or indicators that are addressed in the studies we find for Review Question 5. For Review Question 2, we will focus on identifying relevant measures that are included in the Centers for Medicare & Medicaid

Services (CMS) patient safety measures, AHRQ’s Patient Safety Indicators, or the National Committee for Quality Assurance (NCQA) patient safety related measures. We will ask our content experts to answer Review Questions 3 and 4 by citing selected references, including PSPs used and explanations of the rationale presented in the studies we find for Review Question 5. For Review Questions 6 and 7, we will focus on the barriers, facilitators, and required resources reported in the studies we find for Review Question 5. For Review Question 8, we will identify publicly available patient safety toolkits developed by AHRQ or other organizations that could help to support implementation of the PSPs. To accomplish that task, we will review AHRQ’s Patient Safety Network (PSNet) (<https://psnet.ahrq.gov>) and AHRQ’s listing of patient safety related toolkits (see [https://www.ahrq.gov/tools/index.html?search\\_api\\_views\\_fulltext=&field\\_toolkit\\_topics=14170&sort\\_by=title&sort\\_order=ASC](https://www.ahrq.gov/tools/index.html?search_api_views_fulltext=&field_toolkit_topics=14170&sort_by=title&sort_order=ASC)) and we will include any toolkits mentioned in the studies we find for Review Question 5. We will identify toolkits without assessing or endorsing them.

## Eligibility Criteria for Studies of Effectiveness

We will search for original studies and systematic reviews for Review Question 5 according to the inclusion and exclusion criteria presented in Table 1. As this review focuses on patient safety, we will look for studies and systematic reviews that report on clinical and patient safety outcomes. Work hours and fatigue risk management interventions also have intermediate outcomes for workers (e.g., well-being) and organizations (e.g., turnover and absenteeism), but these are out of scope for the current rapid response.

**Table 1. Inclusion and Exclusion Criteria**

<b>Study Parameter</b>	<b>Inclusion criteria</b>	<b>Exclusion criteria</b>
<b>Population</b>	Clinicians in acute care hospital settings	Non-clinician healthcare workers; Clinicians in settings other than an acute care hospital
<b>Intervention</b>	<i>Modifications to work schedules</i> (duration and structure of hours worked) including: <ul style="list-style-type: none"> <li>• Limitations to total hours worked</li> <li>• Limitations to maximum shift duration</li> <li>• Shift patterns including changes to</li> </ul>	No intervention of interest

<b>Study Parameter</b>	<b>Inclusion criteria</b>	<b>Exclusion criteria</b>
	<p>speed and direction of shift rotations, and recovery time between shifts</p> <p><i>Fatigue risk management practices</i>, including:</p> <ul style="list-style-type: none"> <li>• Sleep hygiene education</li> <li>• Napping</li> <li>• Workplace lighting</li> <li>• Fatigue monitoring, reporting, and incident analysis systems</li> <li>• Pharmacological agents (e.g., caffeine, melatonin, sleep medications)</li> </ul>	
<b>Comparator</b>	Defined time periods (such as historically controlled “before-after” trials) or cohort group(s) of clinicians without work schedule or fatigue risk management intervention.	No defined historical or contemporaneous cohort comparison group
<b>Outcome</b>	<p><i>Patient outcomes</i>:</p> <ul style="list-style-type: none"> <li>• Mortality</li> <li>• Complications</li> </ul> <p><i>Patient safety</i>:</p> <ul style="list-style-type: none"> <li>• Incidence of medical errors or adverse events</li> </ul>	No outcome of interest
<b>Timing</b>	Original studies and systematic reviews published since 2013	Published before 2013
<b>Setting</b>	Acute care hospital setting in the United States	Healthcare settings other than acute care hospitals; For multi-site studies, no site in the United States
<b>Type of studies</b>	Systematic reviews; Randomized controlled trials, non-randomized trials, and observational studies with a comparison group.	Study design not specified, or no control described; Qualitative studies with no quantitative component

## Literature Searches for Studies of Effectiveness

We will search PubMed and the Cochrane Library for systematic reviews published since the MHS II report in March of 2013. If no recent high quality systematic review is identified that fully addresses Review Question 5, we will conduct searches of PubMed for original studies published since 2013.

To efficiently identify articles that meet the eligibility criteria, we will distribute citations from the literature search to team members, with plans to have the title and abstract of each citation reviewed by a single team member. The team will use the DistillerSR AI Classifier Manager as a semi-automated screening tool to conduct the review efficiently at the title and abstract screening stage. The title and abstract of each citation will be

reviewed by a team member, and then the AI Classifier Manager will serve as a second reviewer of each citation.

## **Description of Included Studies**

To efficiently describe eligible studies, the full text of each potentially eligible article will be reviewed by a single team member to confirm eligibility and prepare a summary of the study, including author, year, study design, number of study participants, and main findings relevant to the review questions. Since Review Question 5 calls for identification of studies on the effectiveness of PSPs, we will describe the objectives and basic characteristics of those studies without conducting a detailed analysis of the findings of those studies. The team will decide whether it has enough time and resources to ask a second team member to check a randomly selected 10% sample of the articles to verify that important studies were not excluded and confirm the accuracy of extracted data.

To describe eligible systematic reviews, a single team member will prepare a summary including the author, year, number of studies by study design, and main findings relevant to each of our review questions. For Review Question 8, we will list the name and source of each relevant toolkit along with a 1-2 sentence description of each toolkit. We will not endorse any specific toolkit.

## **Risk of Bias (Quality) Assessment**

For studies that address Review Question 5 about the effectiveness of PSPs, the primary reviewer will use the Cochrane Collaboration's tool for assessing the risk of bias of randomized controlled trials (RCTs) or the ROBINS-I tool for assessing the Risk Of Bias In Non-randomized Studies – of Interventions.<sup>16,17</sup> When assessing RCTs, we will use the 7 items in the Cochrane Collaboration's tool that cover the domains of selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias. When assessing non-randomized studies, we will use specific items in the ROBINS-I tool that assess bias due to confounding, bias in selection of participants into the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the

reported results. The risk of bias assessments will focus on the main outcome of interest in each study.

If we identify a recent eligible systematic review, the primary reviewer will use the criteria developed by the United States Preventive Services Task Force Methods Workgroup for assessing the quality of systematic reviews.<sup>18</sup>

- **Good** - Recent relevant review with comprehensive sources and search strategies; explicit and relevant selection criteria; standard appraisal of included studies; and valid conclusions.
- **Fair** - Recent relevant review that is not clearly biased but lacks comprehensive sources and search strategies.
- **Poor** - Outdated, irrelevant, or biased review without systematic search for studies, explicit selection criteria, or standard appraisal of studies.

The Task Leader will review the risk of bias assessments and any disagreements will be resolved through discussion with the team.

## **EPC Team Disclosures**

EPC core team members must disclose any financial conflicts of interest greater than \$1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest that cumulatively total greater than \$1,000 will usually disqualify EPC core team investigators from participation in the review.

## **Role of the Funder**

This project is funded under Contract No. 75Q80120D00003/75Q80122F32009 from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. The AHRQ Task Order Officer will review contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by AHRQ or the U.S. Department of Health and Human Services.

## **Format and Content of Report**



The report will follow the most recent template approved by AHRQ at the time of approval of the protocol.

## References

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